October 7, 2022

Miha Bodytec GmbH
Felix Schweigert
QA/RA Manager
Siemensstr. 1
Gersthofen, 86368
Germany

Re: K221498
Trade/Device Name: Miha Bodytec II
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF

Dated: September 8, 2022
Received: September 8, 2022

Dear Felix Schweigert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221498

Device Name
miha bodytec II

Indications for Use *(Describe)*

miha bodytec II is a device which performs electronic muscle stimulation based on EMS technology. The device is specifically designed as an addition to other sports and for training muscles.

miha bodytec II is intended to stimulate muscles in order to improve or facilitate muscle performance. In addition it is indicated for the following conditions:

- Re-educating muscles
- Relaxation of muscle spasm
- Retarding or preventing disuse muscle atrophy

The miha bodytec II electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.

miha bodytec II may only be used by persons above the age of 21.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
for
miha bodytec II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

Sponsor

Sponsor: miha bodytec GmbH
Siemensstr. 1
86368 Gersthofen
Germany

Contact Person: Felix Schweigert
fs@miha-bodytec.de
+49 821 45 54 92 - 22

Date Prepared: September 8, 2022

510(k) number: K221498

Device Name and Classification

Proprietary Name: miha bodytec II

Common/Usual Name: Powered muscle stimulator

Classification Name: Stimulator, Muscle, Powered
(21 CFR 890.5850, Product Code NGX and IPF)

Predicate Device

Predicate Device: Primary: miha bodytec II, K201975
Secondary: Katalyst Training System, K190966

Intended Use

miha bodytec II is a device which performs electronic muscle stimulation based on EMS technology. The device is specifically designed as an addition to other sports and for training muscles.

miha bodytec II is intended to stimulate muscles in order to improve or facilitate muscle performance. In addition it is indicated for the following conditions:

- Re-educating muscles
- Relaxation of muscle spasm
- Retarding or preventing disuse muscle atrophy

The miha bodytec II electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.

miha bodytec II may only be used by persons above the age of 21.

Device Description and Function

miha bodytec II is a transcutaneous electrical muscle stimulation (EMS) device which stimulates motor nerves by means of electrical impulses transmitted by electrodes. These excitations of motor nerves are transmitted to the muscle fibers where they stimulate a muscular response. Depending on the parameters of the electrical impulses (pulse frequency, pulse intensity, pulse duration, pulse width, pulse rise, pause time, total session duration), different types of muscle work can be imposed on the stimulated muscles.

miha Bodytec II consists of a control unit mounted on a stand for the selection of programs, setting the parameters and starting/stopping the device, the i-body® electrode vest for applying electrodes to the upper body, i-body® straps for applying electrodes to the arm and legs and the i-body® belt for applying electrodes to the buttocks.

The device encompasses the following variants:

- “Miha bodytec II” control unit connected to the electrodes via cable
- “Miha bodytec II” control unit connected via Bluetooth through the “i-body connect wireless” device”
- “Miha bodytec m.ove” control unit for mobile use connected via Bluetooth through the “i-body connect wireless” device”

The “miha bodytec m.ove” is a lighter version of the “miha bodytec II” device. Almost all electrical components and circuit boards are identical. It shall mainly be used as a mobile solution either with “travel station m.ove” or with “work station m.ove” in medical facilities. It must be connected with the electrode system via the additional wireless stimulation equipment “i-body connect wireless” and has no cable connection.

The “travel station m.ove” is an equipment for the “miha bodytec m.ove” device (not for miha bodytec II) and is supposed to be used as a mobile solution for personal trainers all around the world. It will be used as a “bag” or “suitcase” where the device and the electrodes can be safely stored while travelling and will be used as a stand while the training with the customer is in progress. It has no electronics built in and is mainly made out of textiles, plastics and aluminum.

The “work station m.ove” is an additional equipment for the “miha bodytec m.ove” (not for miha bodytec II) and is supposed to be mainly used in hospitals, physiotherapy facilities and homes for the elderly. It will be used as a transport solution where the device and the electrodes can be safely stored while moving through the facilities and will be used as a stand while the training with the patient is in progress. It has no electronics built in and is mainly made out of wood, plastics and aluminum/steel.

The “i-body connect wireless” is a portable device, which is supposed to be worn at the patient’s body. It has a built in stimulation circuit board and a Bluetooth receiver and produces the stimulation itself while

the main device only acts as a remote control. This way a wireless training / treatment of the trainee / patient is possible. On the one hand, it is a mandatory equipment for the “miha bodytec m.ove” device due to the missing cable connection. On the other hand, it is an additional equipment for the “miha bodytec II” device, which can be used instead of the main connection cable. Through a corresponding software update, the second generation of the device (primary predicate device, K201975) can be changed into a third generation version (subject device, K221498), enabling the wireless functions of the device and thus compatibility with the i-body connect wireless.

miha bodytec II must be used in a professional setting incl. professional sport setting and stationary in closed rooms (clinics, hospitals, nursing homes, doctor’s offices, physical therapists’ private offices). The device must be operated by a trainer who has received a full training from the manufacturer. Before the training, the trainer selects the accessories incl. electrodes in the correct size, applies the electrodes to the athlete/patient i.e. by wearing the electrode vest and connects the straps and belt via cable to the vest and via the “i-body connect wireless” device to the control unit. The trainer can choose between several training programs on the control unit for impulse familiarization, invigoration basic/advanced, muscular endurance and body relax. The intensity can be adjusted by the trainer at the UI of the control unit separately for each channel. Complete body training which addresses all muscle groups is possible with up to 10 pairs of electrodes. Each athlete/patient receives an RFID transponder card for storing training results and individually adjusted programs. Once the training is started, the control unit generates and transmits the electrical signals wirelessly to the “i-body connect wireless” device and thus to the electrodes. miha bodytec II uses bipolar pulses and supplies all channels equally during all programs.
During pulse application, the trainer instructs the athlete/patient on specific exercises to perform. The training can be stopped anytime by pressing the multi-function / stop button.

Predicate Device Comparison

General

Characteristic	New Device	Primary predicate device	Secondary Predicate Device	Similar / Different
510(k) Number	K221498	K201975	K190966	-
Device Name, Model	miha bodytec II (3rd generation)	miha bodytec II (2nd generation)	Katalyst Training System	-
Manufacturer	miha bodytec GmbH	miha bodytec GmbH	Katalyst Inc.	-
Regulation Number	890.5850	890.5850	890.5850	Similar.
Product code	NGX; IPF	NGX; IPF	NGX	Similar between subject and primary predicate device. The Secondary Predicate Device only contains one of the product codes due to its limited indications for use.

Indications for Use	miha bodytec II (MBT II) is a machine with electronic muscle stimulation based on EMS technology. Regarding its use, the device is specifically designed as an addition to other sports and for training muscles. miha bodytec II is intended to stimulate muscles in order to improve or facilitate muscle performance. In addition it is indicated for the following conditions: - Re-educating muscles - Relaxation of muscle spasm - Retarding or preventing disuse muscle atrophy The miha bodytec II electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.	miha bodytec II (MBT II) is a machine with electronic muscle stimulation based on EMS technology. Regarding its use, the device is specifically designed as an addition to other sports and for training muscles. miha bodytec II is intended to stimulate muscles in order to improve or facilitate muscle performance. In addition it is indicated for the following conditions: - Re-educating muscles - Relaxation of muscle spasm - Retarding or preventing disuse muscle atrophy The miha bodytec II electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations ofmotoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.	The Katalyst Training System is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only. The Katalyst Training System is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the training programs or operational parameters are designed to target injured or ailing muscles and its use on such muscles is contraindicated. The Katalyst Training System's electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.	Similar between subject and primary predicate device. Similar between subject and secondary predicate device in terms of indications for use related to the product code NGX. The secondary predicate device does not have listed the IPF related muscle conditioning indications.
Connection of the device to electrodes	<u>miha bodytec II (connection via cable):</u> One stimulation module / control unit which is channel-wise connected to the i-body® electrodes over a cable to the i-body® vest. The electrodes of the i-body® straps and belt are connected via cables to the vest. <u>miha bodytec II (connection via i-body connect wireless):</u> The body worn i-body connect wireless is	One stimulation module / control unit which is channel-wise connected to the i-body® electrodes over a cable to the i-body® vest. The electrodes of the i-body® straps and belt are connected via cables to the vest.	The Impulse Pack connects to the Suit through output cables that terminate with pogo pin connectors. The Suit contains an embedded cable harness which makes connection with the built-in electrodes. Neither the cable harness or the electrodes are removable. The Suit also features leads with snap connectors for	Similar between miha bodytec II (connection via cable) and primary predicate device. Similar between miha bodytec II (connection via i-body connect wireless)/miha bodytec m.ove and secondary

	controlled by the miha bodytec II via Bluetooth and connects to the i-body vest through a short cable. The electrodes of the i-body® straps and belt are connected via cables to the vest. miha bodytec m.ove: The body worn i-body connect wireless is controlled by the miha bodytec m.ove via Bluetooth and connects to the i-body vest through a short cable. The electrodes of the i-body® straps and belt are connected via cables to the vest.		connecting to the arm electrodes	predicate device.
Power Source(s)	miha bodytec II: Control unit: 15 V – 19 V; External power supply (100 – 240 V ~ 50 – 60 Hz) miha bodytec m.ove: Lithium Ion (Li-Ion) rechargeable battery 14.4V, 6900 mAh; Usage via external power supply possible as well (100 – 240 V ~ 50 – 60 Hz) i-body connect wireless: Lithium Ion (Li-Ion) rechargeable battery 7.2V, 2900 mAh	Control unit: 15 V – 19 V; External power supply (100 – 240 V ~ 50 – 60 Hz)	Lithium Polymer (Li-Po) rechargeable battery 7.4V, 2,050 mAh	No difference between miha bodytec II and primay predicate device. Difference between batteries of miha bodytec m.ove/i-body conncect wireless and secondary predicate device due to higher power.
- Method of Line Current Isolation	miha bodytec II: Power Supply in accordance with IEC 60601-1 miha bodytec m.ove: N/A (battery operated device); Usage with power supply: Power Supply in accordance with IEC 60601-1 i-body connect wireless: N/A (battery operated device)	Power Supply in accordance with IEC 60601-1	N/A (battery operated device)	Similar between miha bodytec II and primary predicate device. Similar between miha bodytec m.ove/i-body connect wireless and secondary predicate device.
- Patient Leakage Current	miha bodytec II: < 100 µA miha bodytec m.ove: N/A (battery operated device); Usage with power supply: < 100 µA i-body connect wireless: N/A (battery operated device)	< 100 µA	N/A (battery operated device)	Similar between miha bodytec II and primary predicate device. Similar between miha bodytec m.ove/i-body connect wireless and

				secondary predicate device.
- Normal condition	<u>miha bodytec II:</u> < 100 µA <u>miha bodytec m.ove:</u> N/A (battery operated device); Usage with power supply: < 100 µA <u>i-body connect wireless:</u> N/A (battery operated device)	< 100 µA	N/A (battery operated device)	Similar between miha bodytec II and primary predicate device. Similar between miha bodytec m.ove/i-body connect wireless and secondary predicate device.
- Single fault condition	<u>miha bodytec II:</u> < 100 µA <u>miha bodytec m.ove:</u> N/A (battery operated device); Usage with power supply: < 100 µA <u>i-body connect wireless:</u> N/A (battery operated device)	< 100 µA	N/A (battery operated device)	Similar between miha bodytec II and primary predicate device. Similar between miha bodytec m.ove/i-body connect wireless and secondary predicate device.
Number of Output Modes	One (symmetric biphasic) with 6 training programs	One (symmetric biphasic) with 6 training programs	One (NMES)	Similar.
Number of Output Channels	<u>miha bodytec II (connection via cable):</u> 10, channel selective stimulation. Maximum one channel is active at any time. <u>miha bodytec II (connection via i-body connect wireless):</u> 8, Maximum one channel is active at any time. <u>miha bodytec m.ove:</u> 8, Maximum one channel is active at any time.	10, channel selective stimulation. Maximum one channel is active at any time.	13	No difference between miha bodytec II (connection via cable) with primary predicate device. Difference of all variants in comparison with secondary predicate device.
- Synchronous or Alternating?	Alternating	Alternating	Synchronous, but never 2 channels activated at the same time	Similar
- Method of Channel Isolation	Multiplexed by control unit	Multiplexed by control unit	Multi-Channel High Voltage Analog Switches. Except during channel activation, each	Similar.

			channel is always in high Z state	
Regulated Current or Regulated Voltage?	miha bodytec II (connection via cable): Regulated voltage (all channels) miha bodytec II (connection via i-body connect wireless): Regulated current (all channels) miha bodytec m.ove: Regulated current (all channels)	Regulated voltage (all channels)	Regulated current (all channels)	Similar between miha bodytec II (connection via cable) and primary predicate device. Similar between miha bodytec II (connection via i-body connect wireless)/miha bodytec m.ove and secondary predicate device.
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Similar.
Automatic Overload Trip?	Yes, no load and short circuit conditions are handled	Yes, no load and short circuit conditions are handled	Yes	Similar.
Automatic No-Load Trip?	Yes, no load and short circuit conditions are handled	Yes, no load and short circuit conditions are handled	Yes	Similar.
Automatic Shut Off?	On/Off-Switch, stimulation stops after defined duration, automatic stop of stimulation in case of failure / malfunction detected	On/Off-Switch, stimulation stops after defined duration, automatic stop of stimulation in case of failure / malfunction detected	On/Off-Switch	Similar.
Patient Override Control?	Yes, while a program is active the patient is supervised by a trainer and able to manipulate intensity (amplitude) and push the stop button	Yes, while a program is active the patient is supervised by a trainer and able to manipulate intensity (amplitude) and push the stop button	On/Off-Switch	Similar.
Indicator Display:	Yes	Yes	Yes	Similar.
- On/Off Status?	Yes	Yes	Yes	Similar.
- Low Battery?	miha bodytec II (connection via cable): N/A, no battery miha bodytec II (connection via i-body connect wireless): Yes, indication of i-body connect wireless battery status through miha bodytec II display. miha bodytec m.ove: Yes, indication of miha bodytec m.ove and i-body connect wireless battery	N/A, no battery	Yes	Similar between miha bodytec II (connection via cable) and primary predicate device. Similar between miha bodytec II (connection via i-body connect wireless) / miha bodytec m.ove and

	status through miha bodytec m.ove display.			secondary predicate device.
- Voltage/ Current Level?	Yes, displayed in form of percentage / value range	Yes, displayed in form of percentage / value range	Yes	Similar.
Timer Range / Program Duration (minutes)	Training should not exceed 20 minutes; Screen shows remaining time in minutes and displays image showing time remaining	Training should not exceed 20 minutes; Screen shows remaining time in minutes and displays image showing time remaining	Maximum program: 60 minutes	No difference between subject and primary predicate device. Difference between subject and secondary predicate device.
Number of Programs	11	11	9	Similar
User Interface	Physical buttons and rotary knobs with pictographs of the trained muscles for a quick und usability-oriented setting of the intensity values and multi-functional button for setting, program selection and START/STOP for immediate stimulation stop, power-off button, RFID transponder card placement area. 10.1 inch non-touch LC color display for program / training plan selection via menu, settings, device status , training mode display (animated avatar, timer, selected program)	Physical buttons and rotary knobs with pictographs of the trained muscles for a quick und usability-oriented setting of the intensity values and multi-functional button for setting, program selection and START/STOP for immediate stimulation stop, power-off button, RFID transponder card placement area. 10.1 inch non-touch LC color display for program / training plan selection via menu, settings, device status , training mode display (animated avatar, timer, selected program)	Usage of App with external tablet. Touch display.	Similar between subject and primary predicate device. Difference between subject and secondary predicate device.
Portability / Mobile Use	<u>miha bodytec II (connection via cable):</u> Portable with difficulty, no mobile device, its intended use requires the qualified and trained operator. <u>miha bodytec II (connection via i-body connect wireless):</u> Portable with difficulty, no mobile device, its intended use requires the qualified and trained operator. <u>miha bodytec m.ove:</u> Mobile device	Portable with difficulty, no mobile device, its intended use requires the qualified and trained operator.	Mobile device	Similar between miha bodytec II (connection via cable as well as connection via i-body connect wireless) and primary predicate device. Similar between miha bodytec m.ove and secondary predicate device.
Operator	The device must only be operated by a trainer, who	The device must only be operated by a trainer, who	N/A	No difference between subject and

<table>
<tr><td></td><td>received full training by miha bodytec.</td><td>received full training by miha bodytec.</td><td></td><td>primary predicate device</td></tr>
<tr><td>Compliance with 21 CFR 898?

(Mandatory since May 9, 2000)</td><td>Yes</td><td>Yes</td><td>Yes</td><td>Similar.</td></tr>
<tr><td>Size of electrodes</td><td>Electrodes with pre-defined size of 9.75 – 29.14 in², supplied with the device.

Length x Width of electrode pads:
3,42 - 30,94 in x 3,15 - 4,37 in

<table><tr><td>Vest size</td><td>Size 1 and size V1 in in²</td><td>Size 2, size 3 and size v2 in in²</td></tr><tr><td>2 electrodes for abdomen</td><td>22.85</td><td>27.56</td></tr><tr><td>2 electrodes for chest</td><td>10.31</td><td>12.81</td></tr><tr><td>2 electrodes for upper back</td><td>16.25</td><td>20.98</td></tr><tr><td>2 electrodes for sides of back</td><td>9.75</td><td>11.85</td></tr><tr><td>2 electrodes for lower back</td><td>14.4</td><td>19.47</td></tr></table>
<table><tr><td>Strap size</td><td>Electrode size in²</td></tr><tr><td>Size 1 (pair)</td><td>Each 16.74</td></tr><tr><td>Size 2 (pair)</td><td>Each 20.77</td></tr><tr><td>Size 3 (pair)</td><td>Each 29.14</td></tr></table>
<table><tr><td>belt size</td><td>Electrode size in²</td></tr><tr><td>Size 1 (pair)</td><td>Each 14.7</td></tr><tr><td>Size 2 (pair)</td><td>Each 18.34</td></tr></table></td><td>Electrodes with pre-defined size of 9.75 – 64.36 in², supplied with the device.

Length x Width of electrode pads:
3,42 - 30,94 in x 3,15 - 4,37 in

<table><tr><td>Vest size</td><td>Size 1 and size V1 in in²</td><td>Size 2, size 3 and size v2 in in²</td></tr><tr><td>2 electrodes for abdomen</td><td>22.85</td><td>27.56</td></tr><tr><td>2 electrodes for chest</td><td>10.31</td><td>12.81</td></tr><tr><td>2 electrodes for upper back</td><td>16.25</td><td>20.98</td></tr><tr><td>2 electrodes for sides of back</td><td>9.75</td><td>11.85</td></tr><tr><td>2 electrodes for lower back</td><td>14.4</td><td>19.47</td></tr></table>
<table><tr><td>Strap size</td><td>Electrode size in²</td></tr><tr><td>Size 1 (pair)</td><td>Each 34.15</td></tr><tr><td>Size 2 (pair)</td><td>Each 48.77</td></tr><tr><td>Size 3 (pair)</td><td>Each 64.36</td></tr></table>
<table><tr><td>belt size</td><td>Electrode size in²</td></tr><tr><td>Size 1 (pair)</td><td>Each 14.7</td></tr><tr><td>Size 2 (pair)</td><td>Each 18.34</td></tr></table></td><td>Electrodes with pre-defined size of 4,31 – 83,99 in², supplied with the device.</td><td>Difference between subject and primary predicate device in size of biggest electrode as well as in area size of straps.

Difference between subject and secondary predicate.</td></tr>
</table>

Plugs	<u>miha bodytec II (connection via cable):</u> Main cable with D-Sub 25 pin connector to the control unit and proprietary magnetic connector to the i-body vest. Cables between vest and strap / belt with proprietary connectors. <u>miha bodytec II (connection via i-body connect wireless):</u> Either main cable with D-Sub 25 pin connector to the control unit and proprietary magnetic connector to the i-body vest or the i-body connect wireless connects to the i-body vest with a magnetic pogo pin connector. Cables between vest and strap / belt with proprietary connectors. <u>miha bodytec m.ove:</u> the i-body connect wireless connects to the i-body vest with a magnetic pogo pin connector. Cables between vest and strap / belt with proprietary connectors.	Main cable with D-Sub 25 pin connector to the control unit and proprietary magnetic connector to the i-body vest. Cables between vest and strap / belt with proprietary connectors.	The Impulse Pack connects to the Suit through output cables that terminate with magnetic pogo pin connectors. The Suit also features leads with snap connectors for connecting to the arm electrodes	No difference between miha bodytec II (connection via cable) and primary predicate device. Difference between subject device and secondary predicate device.
Lead wires - cables	<u>miha bodytec II (connection via cable):</u> 1. Main cable with D-Sub 25 pin connector to the control unit and proprietary magnetic connector to the i-body vest. Length: 3000 mm, Polyurethane jacket. 2.1-pole-cables between vest and strap / belt: 15,75 in, 19,29 in, 30,71 in, PVC jacket. 3. Cables within vest: firmly mounted into the vest; Polyurethane jacket Compliant with protected lead wire and patient cable safety requirements <u>miha bodytec II (connection via i-body connect wireless):</u> 1. Main cable with D-Sub 25 pin connector to the control unit and proprietary magnetic connector to the i-body vest. Length: 3000 mm, Polyurethane jacket. 1.1 in i-body connect wireless firmly mounted cable with magnetic connector to the i-body	1. Main cable with D-Sub 25 pin connector to the control unit and proprietary magnetic connector to the i-body vest. Length: 3000 mm, Polyurethane jacket. 2.1-pole-cables between vest and strap / belt: 15,75 in, 19,29 in, 30,71 in, PVC jacket. 3. Cables within vest: firmly mounted into the vest; Polyurethane jacket Compliant with protected lead wire and patient cable safety requirements	1. The Impulse Pack connects to the Suit through output cables that terminate with pogo pin connectors. 2. The Suit features leads with snap connectors for connecting to the arm electrodes 3. The Suit contains an embedded cable harness which makes connection with the built-in electrodes. Neither the cable harness or the electrodes are removable.	Similar

	vest. Length: 900 mm, Polyurethane jacket. 2. 1-pole-cables between vest and strap / belt: 15,75 in, 19,29 in, 30,71 in, PVC jacket. 3. Cables within vest: firmly mounted into the vest; Polyurethane jacket Compliant with protected lead wire and patient cable safety requirements			
	<u>miha bodytec m.ove:</u> 1.1 in i-body connect wireless firmly mounted cable with magnetic connector to the i-body vest. Length: 900 mm, Polyurethane jacket. 2. 1-pole-cables between vest and strap / belt: 15,75 in, 19,29 in, 30,71 in, PVC jacket. 3. Cables within vest: firmly mounted into the vest; Polyurethane jacket Compliant with protected lead wire and patient cable safety requirements			
Conductivity of the electrodes	The athlete needs to put on the genuine and biocompatible miha bodytec undergarments (pants and shirt) under the i-body accessories (vest, strap and belt). The absorbent electrodes covers on the i-body vest, strap and belt need to be moistened using a pump spray bottle with tap water. The electrode vest, straps and belt are washable.	The athlete needs to put on the genuine and biocompatible miha bodytec undergarments (pants and shirt) under the i-body accessories (vest, strap and belt). The absorbent electrodes covers on the i-body vest, strap and belt need to be moistened using a pump spray bottle with tap water. The electrode vest, straps and belt are washable.	The base layer is designed to be worn underneath the suit during training and should have direct contact with your skin. It consists of a shirt and a pair of shorts. Electrode pads of the suit must be wetted with a spray bottle to get the best connectivity for the workouts. The suit is washable.	Similar.
Placement of the electrodes	Appropriately pre-placed in specific areas according to muscle anatomy. Electrodes are firmly mounted into the vest, belt or straps. The electrodes itself cannot be separated from the textile and cannot be exchanged.	Appropriately pre-placed in specific areas according to muscle anatomy. Electrodes are firmly mounted into the vest, belt or straps. The electrodes itself cannot be separated from the textile and cannot be exchanged.	The electrodes are preplaced and firmly mounted into the suit. They are not removable.	Similar.
Material of electrodes	The conductive electrode itself (under the textile) is made out of a 100% BEKINOX Stainless Steel multifilament yarn.	The conductive electrode itself (under the textile) is made out of a 100% BEKINOX Stainless Steel multifilament yarn.	No direct skin contact. Further information not publicly available.	Similar

	No direct skin contact possible.	No direct skin contact possible.		
Maximum duration for use per treatment	Max. 20 minutes per treatment.	Max. 20 minutes per treatment.	Max. 60 minutes.	No difference between subject and primary predicate device. Difference between subject and secondary predicate device.
Accessories	i-body connect wireless i-body vest i-body strap i-body belt Undergarments Transponder card	i-body vest i-body strap i-body belt Undergarments Transponder card	Impulse pack Suit (consists of vest, shorts, arm straps, arm connectors) Base layer	Similar.
Weight	<u>miha bodytec II (connection via cable):</u> Complete: 45.2 lb Control unit: 10.3 lb i-body® with cable set: 3.3 lb i-body® belt: 0.9 lb i-body® strap: 0.44 lb <u>miha bodytec II (connection via i-body connect wireless):</u> Complete: 45.2 lb Control unit: 10.3 lb i-body connect wireless: 1.3 lb i-body® with cable set: 3.3 lb i-body® belt: 0.9 lb i-body® strap: 0.44 lb <u>miha bodytec m.ove:</u> Control unit: 7.5 lb i-body connect wireless: 1.3 lb i-body® with cable set: 3.3 lb i-body® belt: 0.9 lb i-body® strap: 0.44 lb work station m.ove with maximum load: max. 110 lb travel station m.ove with maximum load: max. 55 lb	Complete: 45.2 lb Control unit: 10.3 lb i-body® with cable set: 3.3 lb i-body® belt: 0.9 lb i-body® strap: 0.55 lb	Impulse Pack - 248 g (0,55 lb)	Similar between miha bodytec II (connection via cable) and primary predicate device. Difference between subject and secondary predicate device.

Dimensions (ft.) [W x H x D]	<u>miha bodytec II (connection via cable):</u> Control unit: 1.39 × 0.89 × 0.23 (W × D × H in ft) Complete: 1.77 × 1.69 × 3.89 (W × D × H in ft) <u>miha bodytec II (connection via i-body connect wireless):</u> Control unit: 1.39 × 0.89 × 0.23 (W × D × H in ft) Complete: 1.77 × 1.69 × 3.89 (W × D × H in ft) i-body connect wireless: 0.29 × 0.38 × 0.18 (W × D × H in ft) <u>miha bodytec m.ove:</u> Control unit: 1.39 × 0.95 × 0.23 (W × D × H in ft) i-body connect wireless: 0.29 × 0.38 × 0.18 (W × D × H in ft) work station m.ove: 1.83 × 3.12 × 3.74 (W × D × H in ft) travel station m.ove: 1.60 × 0.98 × 3.15 (W × D × H in ft)	Control unit: 1.39 × 0.89 × 0.23 (W × D × H in ft) Complete: 1.77 × 1.69 × 3.89 (W × D × H in ft)	Impulse Pack – 148x78 mm (0,49x0,26 ft) Connector 1 – 65x32mm (0,21x0,10 ft) Connector 2 – 56x32mm (0,18x0,10)	No difference between miha bodytec II (connection via cable) and primary predicate device. Difference between subject and secondary predicate device.
Housing Materials and Construction	<u>miha bodytec II (connection via cable):</u> Control unit: Aluminum <u>miha bodytec II (connection via i-body connect wireless):</u> Control unit: Aluminum i-body connect wireless: Plastic injection molding <u>miha bodytec m.ove:</u> Control unit: Plastic injection molding i-body connect wireless: Plastic injection molding	Control unit: Aluminum	Plastic injection molding	No difference between miha bodytec II (connection via cable) and primary predicate device. Similar between miha bodytec II (connection via i-body connect wireless) and primary predicate device. Similar between miha bodytec m.ove and secondary predicate device.
Standards	ISO 14971:2007 AAMI ANSI ES 60601-1_2005/(R)2012 And A1:2012 IEC 60601-1-2:2014 IEC 60601-1-11:2010	ISO 14971:2007 AAMI ANSI ES 60601-1_2005/(R)2012 And A1:2012 IEC 60601-1-2:2014 IEC 60601-1-11:2010	ISO 14971:2007 AAMI ANSI ES 60601-1_2005/(R)2012 And A1:2012 IEC 60601-1 IEC 60601-1-2	Similar.

	IEC 60601-2-10:2012 IEC 62304:2015 ISO 10993-5:2009 ISO 10993-10:2010	IEC 60601-2-10:2012 IEC 62304:2015 ISO 10993-5:2009 ISO 10993-10:2010	IEC 60601-2-10 IEC 62304:2015 ISO 10993-5:2009 ISO 10993-10:2010 IEC 62133:2012	

Table 1: Basic Device Characteristics – Comparison with Predicate Device

Output Specifications

Characteristic	New Device	Primary Predicate Device	Secondary Predicate Device	Similar / Different
Waveform	Symmetric biphasic	Symmetric biphasic	Symmetric biphasic	Similar.
Shape	Rectangular	Rectangular	Rectangular	Similar.
Maximum Output Voltage	miha bodytec II (connection via cable): <= 74Vp @ 500Ω (54 - 74 Vp) <= 152Vp @ 2kΩ (110 … 152 Vp) <= 152Vp @ 10kΩ (130 … 152 Vp)	<= 74Vp @ 500Ω (54 - 74 Vp) <= 152Vp @ 2kΩ (110 … 152 Vp) <= 152Vp @ 10kΩ (130 … 152 Vp)	60 V @ 500 Ω 100 V @ 2 kΩ 100 V @ 10 kΩ	No difference between miha bodytec II (connection via cable) and primary predicate device. Difference between miha bodytec II (connection via i-body connect wireless), miha bodytec m.ove and primary predicate device as well as between all subject devices and secondary predicate device.
	miha bodytec II (connection via i-body connect wireless): <= 76,2Vp @ 500 Ω (74,32 – 76,2Vp) <= 111Vp @ 2 kΩ (107,36 – 111Vp) <= 117Vp @ 10 kΩ (101,5 – 117Vp)			
	miha bodytec m.ove: <= 76,2Vp @ 500 Ω (74,32 – 76,2Vp) <= 111Vp @ 2 kΩ (107,36 – 111Vp) <= 117Vp @ 10 kΩ (101,5 – 117Vp)			
Maximum Output Current	miha bodytec II (connection via cable): < 148mAp @ 500Ω (108-148mAp) < 76mAp @ 2kΩ (55-76mAp) < 15 mAp @ 10kΩ (13-15mAp)	< 148mAp @ 500Ω (108-148mAp) < 76mAp @ 2kΩ (55-76mAp) < 15 mAp @ 10kΩ (13-15mAp)	120 mA @ 500 Ω 50 mA @ 2 kΩ 10 mA @ 10 kΩ	No difference between miha bodytec II (connection via cable) and primary predicate device. Difference between miha bodytec II (connection via i-body connect wireless), miha bodytec m.ove and primary predicate device as well as between all subject devices and
	miha bodytec II (connection via i-body connect wireless): < 152,4mAp @ 500 Ω (148,63 – 152,4mAp) < 55,5mAp @ 2 kΩ (53,68 – 55,5mAp)			

	< 11,7mAp @ 10 kΩ (10,15 – 11,7mAp) miha bodytec m.ove: < 152,4mAp @ 500 Ω (148,63 – 152,4mAp) < 55,5mAp @ 2 kΩ (53,68 – 55,5mAp) < 11,7mAp @ 10 kΩ (10,15 – 11,7mAp)			secondary predicate device.
Pulse Width	50 - 400 µs	50 - 400 µs	250 - 375 µs	No difference between subject device and primary predicate device. Similar between subject device and secondary predicate device in terms of maximum pulse width. Difference between subject device and secondary predicate device in terms of minimum pulse width.
Frequency (Hz)	miha bodytec II (connection via cable): 2 - 150 Hz miha bodytec II (connection via i-body connect wireless): 2 - 100 Hz miha bodytec m.ove: 2 - 100 Hz	2 - 150 Hz	1 - 105 Hz	No difference between miha bodytec II (connection via cable) and primary predicate device. Similar between miha bodytec II (connection via i-body connect wireless), miha bodytec m.ove and secondary predicate device
Symmetrical phases?	Yes	Yes	Yes	Similar.
Phase Duration	25 … 200 µs	25 … 200 µs	250 … 375 µs	No difference between subject device and primary predicate device. Difference between subject device and secondary predicate device.
Maximum Phase Charge	miha bodytec II (connection via cable): <32 µC @ 500Ω miha bodytec II (connection via i-body connect wireless):	<32 µC @ 500Ω	45 µC @ 500Ω	No difference between miha bodytec II (connection via

	< 30,48 µC @ 500Ω miha bodytec m.ove: < 30,48 µC @ 500Ω			cable) and primary predicate device. Difference between miha bodytec II (connection via i-body connect wireless), miha bodytec m.ove and primary predicate device as well as between all subject devices and secondary predicate device.
Maximum Current Density	miha bodytec II (connection via cable): 0.64 mA/cm² @ 500Ω miha bodytec II (connection via i-body connect wireless): 0,42 mA/cm² @ 500 Ω miha bodytec m.ove: 0,42 mA/cm² @ 500 Ω	0.64 mA/cm² @ 500Ω	1.15 mA/cm² @ 500Ω	No difference between miha bodytec II (connection via cable) and primary predicate device. Difference between miha bodytec II (connection via i-body connect wireless), miha bodytec m.ove and primary predicate device as well as between all subject devices and secondary predicate device.
Maximum Power Density	miha bodytec II (connection via cable): 0.82 mW/cm² @ 500Ω miha bodytec II (connection via i-body connect wireless): 5,47 mW/cm² @ 500 Ω miha bodytec m.ove: 5,47 mW/cm² @ 500 Ω	0.82 mW/cm² @ 500Ω	22.68 mW/cm² @ 500Ω	No difference between miha bodytec II (connection via cable) and primary predicate device. Difference between miha bodytec II (connection via i-body connect wireless), miha bodytec m.ove and primary predicate device as well as between all subject devices and secondary predicate device.
Burst Mode	Contraction time: 1 – 10 s Relaxation time: 0.0 – 10 s	Contraction time: 1 – 10 s Relaxation time: 0.0 – 10 s	N.A.	No difference between subject and primary predicate device.

Safety circuits	miha bodytec II (connection via cable): Short-circuit monitoring, watchdog monitoring, no load trip, onload trip, button for immediate shut off, redundant hardware error monitoring (emergency STOP option) Firmware self-tests.	Short-circuit monitoring, watchdog monitoring, no load trip, onload trip, button for immediate shut off, redundant hardware error monitoring (emergency STOP option) Firmware self-tests.	N.A.	Similar between subject devices and primary predicate device.
	miha bodytec II (connection via i-body connect wireless): Overcurrent monitoring, channel monitoring, watchdog monitoring, button for immediate shut off, redundant hardware error monitoring (emergency STOP option) Firmware self-tests, firmware no load detection			
	miha bodytec m.ove: Overcurrent monitoring, channel monitoring, watchdog monitoring, button for immediate shut off, redundant hardware error monitoring (emergency STOP option) Firmware self-tests, firmware no load detection			

Table 2: Output Specifications – Comparison with Predicate Devices

Performance Testing

Electrical Safety and Electromagnetic Compatibility testing: miha bodytec II was tested according to and is in compliance with recognized standards for electrical safety and electromagnetic compatibility.

Software and System validation: The miha bodytec II comprises firmware which was verified and validated according to IEC 62304 and FDA's guidance: General Principles of Software Validation. Software validation demonstrated that the firmware met the software system requirements. The full system validation testing also included testing in accordance with the recommendations of FDA's "Guidance Document for Powered Muscle Stimulator 510(k)s" issued on June 9, 1999. Oscilloscope tracings were obtained of the device output waveforms under maximum supported voltage and pulse widths under loads of 500 Ω, 2 kΩ and 10 kΩ. Additional System-level tests were conducted, including electrical tests of the interfaces, thermographic inspections, tests in climate chamber, shock and vibration tests.

Usability validation: The overall system was validated to confirm that the device meets its intended use, i.e. can be used safe and effectively by the specified users within the specified use environment, taking into account human factors and usability requirements.

Shelf life and dispersion testing:
Bench testing of the electrodes was performed to demonstrate uniform current distributions (dispersion testing). The test case was built up according to FDA's requirements.
4 batches of electrodes were tested. From each batch 8 chest-electrodes, 8 lateral back-electrodes, 1 upper back-electrode and 1 abdomen-electrode were selected. The electrodes were cut out of the vest and moistened to be covered by the undergarments. 8 measure points from each chest-electrode, each lateral back-electrode and each upper back-electrode as well as 5 measure points from each abdomen-electrode were defined. As indicated by FDA the electrodes were measured prior to and after cleansing. After this measuring period the accelerated aging was applied and followed by another measuring period which was conducted exactly the same like the first one. All tests successfully passed.
To calculate the shelf life, we establish new testing according to ASTM F1980-16. In a climate cabinet an accelerating aging condition for the electrodes was simulated at 60°C for 10 weeks. Through testing the electrical resistance of the electrodes, a 3-year storage was tested. Altogether 10 electrodes and 6 contact points were tested. All tests were successfully passed.

Performance Standards

miha bodytec II complies with the applicable requirements of the following international and national standards:

- IEC 60601-2-10:2016 - Medical Electrical Equipment -- Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators
- IEC 60601-1-2:2014 - Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- AAMI ANSI ES 60601-1_2005/(R)2012 And A1:2012 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-11:2015 - Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62304:2006 + A1:2015 - Medical Device Software - Software Life Cycle Processes
- ISO 14971:2007 - Medical Devices - Application Of Risk Management To Medical Devices
- IEC 62366-1:2015 + COR1:2016 - Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices
- ISO 10993-5:2009 - Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2010 - Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ASTM F1980-16 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ANSI IEEE C63.27-2017 - American National Standard for Evaluation of Wireless Coexistence

The following FDA Guidance Documents have been applied:

- Guidance Document for Powered Muscle Stimulator 510(k)s, Document issued on: June 9, 1999
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on: May 11, 2005
- General Principles of Software Validation issued on: January 11, 2002
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Document issued on: June 14, 2013
- Cyber security for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, Document issued on: January 14, 2005
- Off-the-Shelf Software Use in Medical Devices, Document issued on: September 27, 2019
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Document issued on: September 4, 2020
- Radio Frequency Wireless Technology in Medical Devices, Issued August 13, 2013, Document issued on: August 14, 2013
- Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices, Document issued on: July 11, 2016.

Conclusion

None of the differences identified raise any new issues regarding safety or effectiveness. Therefore, we conclude that miha bodytec II (3rd generation) is substantially equivalent to the primary predicate device miha bodytec II (2nd generation) as well as the secondary predicate device Katalyst Training System.